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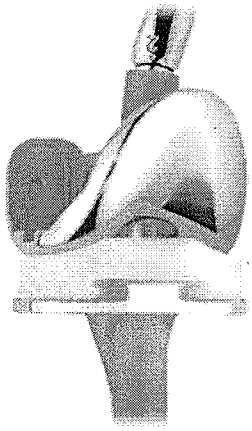
KNEE

NexGen® RH Knee



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Product Description

The *NexGen* RH Knee features a modular hinge mechanism that results in 95% of the load being carried by the tibial condyles,[1] similar to the loading pattern of a primary implant design.

Because the femoral condyles remain centered on the tibia throughout the range of motion, and the shape of the patellar groove is similar to the design of the *NexGen* system, patella tracking is similar to a primary knee design.

For the more challenging arthroplasty procedures, the *NexGen* RH Knee can be used in conjunction with the *Trabecular Metal*™ Tibial and Femoral Cones* that address those most difficult bone-loss scenarios.

Since the *NexGen* RH Knee takes advantage of modular design by using *NexGen* Augments, the basic bone cuts are the same as those made for *NexGen* Primary System Components. This helps to minimize bone loss and allows use of instrumentation commonly used in primary implant procedures.

*Must be used with bone cement when used in conjunction with the *NexGen* RH Knee.

Patello-femoral Kinematics

The *NexGen* RH Knee Femoral Component has the same patello-femoral design as the other *NexGen* Femoral Components. The groove allows the patella to track deeply — similar to an anatomic patella. The patella is fully supported up to 60° of flexion. The central location of the hinge axis keeps the femoral condyles in a consistent sagittal plane. This allows for more normal patellar tracking since the patella does not shift posteriorly during flexion.

Designed to Limit Impact, Resist Subluxation

To resist subluxation, the *NexGen* RH Knee locking mechanism design offers a minimum "jump height" of 40 mm.

The ratio of conformity between the femoral condyles and the highly dished tibial articular surface is virtually 1 to 1. By maximizing contact area, the stresses in the polyethylene are distributed across a larger surface area.

Contact occurs on the frontal radius of the *NexGen* RH Knee Femoral Component with the articulating surface just as the implant moves to hyperextension. This will cause the knee to distract slightly, dampening the extension impact. This interaction was designed to dissipate the hyperextension force.

Pivot/Rotation

The central location of the *NexGen* RH Knee hinge mechanism is placed closer to the axis of the tibial component, resulting in more natural and consistent tibio-femoral kinematics when compared to posterior hinge knee designs. The rotation of the *NexGen* RH Knee platform is designed to displace torsional loads from the cement interfaces to the soft tissues, since it allows up to 25 degrees of movement in internal and external rotation.

Modularity of Hinge Pin/Locking Mechanism

The modularity of the hinge post extension pin allows the implantation to proceed without requiring the knee to be excessively distracted or held while the components are assembled. The *NexGen* RH Knee Femoral and Tibial Components are cemented into position, and, with minimal distraction, the tibial articular surface is rotated into position. The hinge post extension is easily inserted into the tibial baseplate and tightened.

95% Condylan Loading

In many conventional rotating hinge knee designs, the hinge bears the majority of the compressive load until full extension is achieved. Designs that have the center of rotation located posteriorly can cause "booking" of the joint, which may result in stress on the cement interfaces or accelerated polyethylene-bearing wear in the hinge. The *NexGen* RH Knee addresses these concerns as the RH Knee femoral component and articular surfaces are designed to maintain centralized contact throughout ROM (from -3° of hyperextension to 120°). The patented hinge design features passes 95% of the load through the tibial condyles.

Cleaning Instructions

Sterility
Gamma irradiation is indicated by the symbol on the labeling. These devices remain sterile as long as the package integrity has not been violated. Inspect each package prior to use and do not use the component if any seal or cavity is damaged or breached or if the expiration date has been exceeded. Once opened, the component must be used, discarded, or resterilized.

Resterilization Instructions
These sterilization instructions are consistent with ANSI/AAMI/ISO standards and guidelines. They should be used for items supplied non-sterile, for reprocessing reusable devices, or for sterile items that were opened but unused. See Zimmer booklet 97-5000-170-00 (available from your distributor) for detailed sterilization guidelines for reusable instruments and provisionals.

Solid metal implants may be resterilized only once for immediate use, in the event of inadvertent loss of sterility while preparing for surgery. This is subject to the exceptions listed below.

DO NOT RESTERILIZE

- Single-use-only components that have been contaminated with body fluids or debris or that have been previously implanted
- *Trabecular Metal*™ Technology components
- Components containing UHMWPE
- Components containing PMMA

Do not use the original plastic cavities or lids for resterilization. Single devices may use a standard polyethylene or Tyvek® pouch. Ensure that the pouch is large enough to contain the devices without stressing the seals or tearing the pouch.

Do not stack heavy items on top of any sterilization cases made from plastic. The resulting deformation can cause cracking of the plastic material.

Rinse porous components to remove lint or debris (using USP purified water).

Aggressive cleaning with detergents and brushes may damage special features of the implant, such as fiber metal pads or bead coatings. Also, certain detergents may be difficult to rinse off polymer items, especially those made of silicone rubber.

Items made from titanium and titanium alloys can form oxide layers from steam boiler treatment chemicals or detergent residues. While these oxides are biocompatible, they can obliterate etchings and stampings.

Modular implant components must be sterilized separately to minimize potential bioburden buildup in the dead space and expansion/contraction stresses.

Product Brochure

NexGen RH Knee

The test evaluated the amount of contact that occurs between the *NexGen* RH Knee Femoral Component and articular surface. The large condylar contact patches confirm that the load stays toward the central portion of the tibial articular surface throughout ROM.

In many conventional rotating hinge knee designs, the hinge bears the majority of the compressive load until full extension is achieved. Designs that have the center of rotation located posteriorly can cause "booking" of the joint, which may result in stress on the cement interfaces or accelerated polyethylene-bearing wear in the hinge. The *NexGen* RH Knee addresses these concerns, as the RH Knee Femoral Component and articular surface are designed to maintain centralized contact throughout ROM (from -3 degrees of hyperextension to 120 degrees of flexion). The patented hinge design feature passes 95% of the load through the tibial condyles.[1]

Reference

1. Data on file at Zimmer. The results of these tests have not been shown to correlate with clinical mechanisms.

Indications

This device is indicated for patients with moderate to severe knee instability, significant bone loss and/or ligament deficiencies caused by neoplasms, trauma, rheumatoid arthritis, osteoarthritis, traumatic arthritis, polyarthritis, collagen disorders, and/or avascular necrosis of the femoral condyle, valgus, varus, or flexion deformities, the salvage of previously failed surgical attempts.

This device is intended for cemented use only.

Individualization of Treatment

To properly match the components, the femoral and tibial component size must both be reflected on the articular surface label. Mismatching may result in poor surface contact and cause pain, greater wear, or implant instability, or otherwise reduce implant life.

Use only instruments and provisionals specifically designed for use with these devices to help ensure accurate surgical implantation, soft-tissue balancing, and evaluation of knee function.

Selection of polyethylene components is a matter of physician discretion. Thicker polyethylene components may be needed if the patient is young, heavy, and/or physically active.

Contraindications

Contraindications include:

Previous history of infection in the affected joint and/or local/systemic infection that may affect the prosthetic joint, skeletal immaturity, neuropathic arthropathy, osteoporosis or any loss of musculature or neuromuscular disease that compromises the affected limb, a stable, painless arthrodesis in a satisfactory functional position.

Total knee arthroplasty is contraindicated in patients who have rheumatoid arthritis (RA) and an ulcer of the skin or a history of recurrent breakdown of the skin because their risk of postoperative infection is greater. RA patients using steroids may also have increased risk of infection. Late infections in RA patients have been reported 24+ months postoperative.

WARNINGS

This device is for single patient use only. Do not reuse.

Do not reinsert an articular surface implant that has been inserted previously. There may be visually nondetectable flaws that could reduce the service life of the implant.

Do not use:

- This product for other than labeled indications (off-label use)
- Any component if damage is found or caused during setup or insertion
- Components from other knee systems (and vice versa) unless expressly labeled for such use. Premature wear or loosening may develop and may require surgical explantation
- Micro-sized patellas with the Rotating Hinge Knee. Excessive wear may result
- 26 or 29 mm-sized standard patellas with B, C, D, E, or F femoral components unless used in an inset mode. Excessive wear may result

Because the RH Knee is a highly constrained device, the risk of component breakage, loosening, and polyethylene wear may be greater than for less constrained knee implants.

Stem extensions are required for both the femoral and tibial components when being used as a revision knee system.

The risk of implant failure is higher with inaccurate component alignment or positioning.

Soft tissues should be balanced and components' positioning should be confirmed to minimize edge loading.

Fat embolism risk is increased with intramedullary instrumentation and/or cement pressurization. Consider venting the femur or tibia.

With simultaneous bilateral knee surgery, release leg tourniquets 10 minutes apart to lessen any lung insult that may occur.

PRECAUTIONS

- Avoid notching, scratching, or striking the device
- The potential for deep sepsis can be minimized by using biocontamination controls. Continued surveillance for new or recurrent sources of infection should be continued as long as the device is in place.

ADVERSE EFFECTS

- Loosening or fracture/damage of the prosthetic knee components or surrounding tissues
- Dislocation and/or joint instability
- Malalignment of the prosthetic knee components
- Bone fracture or nerve damage
- Swelling or infection
- Leg length discrepancies
- Poor range of motion
- Pain
- Venous thromboembolic disease
- Inflammation
- Metal sensitivity
- Corrosion of metal components (the significance and long-term implications are uncertain and await further clinical evidence and evaluation)

Zimmer® Segmental System

The Segmental System is a modular system

Zimmer® Trabecular Metal™ Femoral and Tibial Cone Augments

Zimmer® Trabecular Metal™ Femoral and Tibial Cone Augments can be an alternative to grafting procedures

MOST Options® System for Severe Bone Loss

The MOST Option System provides the potential for limb restoration and function

Zimmer® Trabecular Metal™ Augmentation Patella

The Augmentation Patella compensates for defects in the patella during revision TKA

Zimmer® NexGen® Trabecular Metal™ Primary Patella

The NexGen® Trabecular Metal™ Primary Patella is a porous patella